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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,662	01/30/2001	Albert Zorko Abram	A33760PCTUSA	3549

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EXAMINER
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OSTRUP, CLINTON T

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 03/18/2002

1/1

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/719,662

Applicant(s)

ABRAM, ALBERT ZORKO

Examiner

Clinton Ostrup

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 December 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

Claims 1-32 are pending in this application.

### **Response to Applicant's Arguments/Amendment**

The Applicant's arguments filed December 14, 2001, Paper No. 12, to the rejection of claims 4-6 and 9 under 35 U.S.C. 112, second paragraph have been fully considered and deemed persuasive. Therefore, the said rejection has been withdrawn.

The Applicant's arguments filed December 14, 2001, Paper No. 12, to the rejection of claims 1-6, 9-11, 16, and 18 under 35 U.S.C. 102(b) as being anticipated by Breton et al. and the rejection of claims 1-18 under 35 U.S.C. 103(a) have been fully considered, however, they are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. *12, 11, 15, 26, 30*

Claims 1-10, 12-14, 16-25, 27-29, and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis 5,143,717 and further in view of Woodford et al., Bioavailability and Activity of Topical Corticosteroids for a Novel Drug Delivery System, the Aerosol Quick-Break Foam.

Davis teaches an antibiotic, water-soluble foam and a dispenser system for applying said foam. The reference teaches using white petrolatum, distilled water, alcohols and hydrocarbon propellant gas mixtures to deliver the active ingredient silver sulfadiazine. The reference teaches the use of fatty alcohols, emollients, emulsifiers, humectants, as well as the addition of other ingredients including steroid preparations.

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Although the primary reference teaches an aerosol foam comprising the occlusive agent petrolatum, aqueous and organic solvents, propellants, and emulsifiers and surfactants, it lacks an active ingredient which is insoluble in both water and the occlusive agent.

Woodford et al., teach topically applied bioactive aerosol quick-break foams in aqueous-alcoholic systems comprising a non-ionic wax, moisturizers, and propellants. The reference teaches the specific corticosteroids, betamethasone valerate and clobetasol propionate as useful in the invention. The secondary reference teaches that the quick-break aerosol foam offers several advantages including ease of application, controlled dosage from a metered valve, economy in use, suitability for smooth or hairy skin, <sup>and</sup> reduced inhalations as compared to other aerosol sprays.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the topical antibacterial foam of Davis, by adding corticosteroids as taught by Woodford et al., because of the expectation of obtaining a quick-break aerosolized foam composition which could be used to deliver skin treatment compositions in a safe, economic way.

Claims 1-14, 16-29, and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis 5,143,717, Woodford et al., Bioavailability and Activity of Topical Corticosteroids for a Novel Drug Delivery System, the Aerosol Quick-Break Foam as applied to claims 1-10, 12-14, 16-25, 27-29, and 31-32 above and further in view of Jones et al., **WO 96/27376**.

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Although the combination of references above teach a topically applied quick-break bioactive foam as described above, they lack the specific emulsifier as claimed instantly in claims 11 and 26.

Jones et al., teach a quick-break foamable pharmaceutical composition comprising a corticosteroid, a quick-break foaming agent, a propellant and a buffering agent. The Jones reference teaches as an Example betamethasone valerate, water, alcohol, and the specific emulsifier of instant claims 11 and 26, Polysorbate 60 and teaches that polysorbate 60 is particularly preferred because it enhances the fatty alcohol solubility in the system and enhances foam formation.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the quick-break foam composition of the combined references above by adding polysorbate 60 as taught by Jones et al., because of the expectation of obtaining a quick-break foam with an emulsifier that enhances the foam and the fatty alcohol solubility.

Claims 1-10, 12-25, 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis 5,143,717 and Woodford et al., Bioavailability and Activity of Topical Corticosteroids for a Novel Drug Delivery System, the Aerosol Quick-Break Foam as applied to claims 1-10, 12-14, 16-25, 27-29, and 31-32 above and further in view of Gers-Barlag et al. 5,833,960.

Although the combination of references above teach a topically applied quick-break bioactive foam as described above, they lack the cosolvent of instant claims 15 and 30.

Gers-Barlag et al. describe foaming, light protection preparations and a method of using them to protect skin from harmful wavelengths of light. See: abstract and col. 12, line 37- col. 13, line 11. Foams, according to the secondary reference, allow a fine distribution of substances onto the skin. See: col. 9, lines 3-28. The secondary reference describes the oil phase as comprising 1%-50% by weight of the preparation. See: col. 15, lines 24-27. The secondary reference describes mixtures of C<sub>12-15</sub>-alkyl benzoates, the specific organic solvent of claim 15, and other compounds as particularly advantageous in the oil phase. See: col. 14, line 60 – col. 15 line 5.

The secondary reference teaches the use of aerosol container and an amount of 5.00% by weight of a propellant (butane/isobutane/propane). Thus, meeting the specific limitations of claim 17. See: col. 16, Example 3. Further, the reference teaches the addition of water to an aqueous phase to make the composition have a sum total of 100.00% by weight. The amount of water added to the formulation meets the specific limitations of claim 13. See: col. 15, line 28 - col. 16, line 68.

Gers-Barlag et al. further describe less soluble components in the formulation as having better spreadability than in formulations known in the art. See: col. 9, lines 9-14. The secondary reference describes the formulation as having "particularly good skin compatibility, making it possible to spread valuable ingredients particularly well on the skin." See: col. 9, lines 15-29.

It would have been obvious to one having ordinary skill in the art, at the time the invention was made, to have modified the quick-break aerosol skin treatment foam compositions of the combined references by adding the amounts of aqueous solvent

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and propellant as well as the alkyl benzoates as taught by Gers-Barlag et al. because of the expectation of obtaining an aerosol foam skin treatment composition which provides good skin compatibility and makes it possible to spread valuable, less soluble ingredients particularly well on the skin.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on M-F (8:30am-5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Clinton Ostrup  
Examiner  
Art Unit 1614

March 15, 2002

FREDERICK KRASS  
PRIMARY EXAMINER  
GROUP 1600

